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# **The Effectiveness of Strengthening Exercises on HIV Positive Patients**

A Literature Review.

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People living with HIV/AIDS (PLWHA) are more prone to get frequent disabilities, cardiorespiratory issues, neurological conditions and musculoskeletal problems during their stages of infection and sometimes during Antiretroviral therapy treatments. Musculoskeletal conditions are one of the major issues for HIV positives and it can be treated with strengthening exercises and other treatments. This study offers a few assets for physiotherapists and physiotherapy students who are interested in expanding their knowledge in strength training for HIV positive clients.

The aim of the study was to investigate the effects of strength training on the muscle mass, muscle strength, muscle mass, body weight, BMI and body fat in HIV positive patients.

A Literature review is the chosen method. Six full articles were selected. This thesis is based on randomized control trials with HIV positive patients who were between 18 to 70 years old.

All the studies had different protocols and durations for their interventions. Five articles reported, that due to strength training there was a significant improvement in muscle strength and muscle mass. Only one study considered endurance as an outcome and found endurance was increasing with the resistance training. Though all the studies had included body weight and BMI as outcomes, it was difficult to have a final conclusion about effects on body weight and BMI. Furthermore, majority of the studies found that there is a possible co-relation between strengthening exercises and reducing body fat on PLWHA.

In conclusion, strengthening exercises remarkably increased muscle mass, muscle strength, endurance, and reduction in body fat. But there were not any fixed conclusion for Body weight and BMI.

Keywords	Strength training, Muscle strength, Muscle mass, BMI, Body Fat HIV/AIDS, Rehabilitation.

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## 1 Introduction

HIV is a virus that infects and weakens the immune system, impairing or destroying its functions and ultimately leading to acquired immunodeficiency syndrome (AIDS). According to the UNAIDS terminology guideline, a person who is HIV positive has had antibodies against HIV. It will be detected from blood test or gingival exudate test (UNAIDS Terminology Guideline, 2015).

HIV symptoms will differ according to its stage. After initial infection, the first few weeks it can be asymptomatic or show symptoms such as fever, rash, headache or a sore throat. Since HIV will depress the immune system with time, HIV positive patients can progress signs and symptoms including loss of weight, edematous lymph nodes, cough and fever. Due to lack of proper treatments, they are more prone to progress severe illnesses including tuberculosis, severe bacterial infections, lymphomas, and HIV wasting syndrome (World Health Organization, 2006). Antiretroviral therapy (ART) is considered as the main pharmacological treatment for the HIV positives. It is a viral replication which is really active and suppressing. Due to ART the amount of virus in the blood will be reduced and it will slow down the progression of HIV (UNAIDS Terminology guideline, 2015).

According to WHO and UNAIDS estimation, 36.7 million people were living with HIV in the world, 1.8 million people have become newly infected and 1 million died due to HIV associated causes at the end of 2016. From 36.7 million HIV positives more than 90% are taking lifelong Antiretroviral Therapy (ART). Globally, Adults–54%, children - 43% and 76% of breastfeeding and pregnant women with HIV are taking ART globally. Africa is considered the most affected region for HIV and it accounts for nearly two third of the sum of new HIV positives around the world. Moreover, 70% of HIV positive people know their status and the goal is to increase the awareness about their status up to 90%. Also, 7.5 million population still require to access HIV testing services in the world (GLOBAL AIDS UPDATE 2016, 2016).

There are many ways physiotherapists can approach the HIV patients in order to increase their quality of life. HIV patients have many symptoms and adverse effects of treatments. In order to prevent or control the adverse effect and symptoms physiotherapists are commonly using strengthening exercises, to identified the effect on BMI, muscle mass, muscle strength and endurance.

Because of all these reasons, it is essential to consider particularly strength training for HIV positive patients (Roubenoff, 2000), (Hand et al., 2009), (Yarasheki et al., 2001).

The aim of this study is to investigate the effectiveness of strength training which is used for HIV positives. Randomized Control Trials which are relevant to the topic were used to assess the effects of strength training.

## **2 Literature review**

### **2.1 HIV and Physiotherapy**

Though Highly Active Antiretroviral Therapy (HAART) could improve their life expectancy, People Living with HIV/AIDS (PLWHA) are more prone to get frequent disabilities, cardiorespiratory issues, neurological conditions and musculoskeletal problems during their stages of infection and sometimes during ART treatments. However, there are other conditions which also cause the episodic disabilities such as lupus arthritis, multiple sclerosis, some cancer, diabetes, psychological problems, amongst others. It is difficult to know the causes of frequent disabilities. The rehabilitation programs are taking a major role in PLWHA, to maintain their health and quality of life, to improve the manpower in their workplace, and to be active in their social and family life. Among HIV positives, 72% are having the noninfectious musculoskeletal complications. The common symptoms of noninfectious musculoskeletal conditions include osteoporosis, joint disease, myopathies and metabolic disorders. Loss of lean body mass is one of the major complications with PLWHA, which is commonly seen in muscle atrophy of limbs. The other major anthropometric change is the redistribution of body fat. This is significantly seen in the accumulation of abdominal fat (Pullen et al., 2014).

Therefore, physiotherapy is often used for managing and preventing the different conditions at different stages of HIV. Until now, physiotherapy has shown significant effects on functional limitation, physical impairment and their quality of life. (Pullen et al., 2014) Furthermore, physiotherapists take a major

position to manage and prevent the condition which is interconnected with less amount of Physical activity, including AIDS/HIV. Although there are many pioneers, a physical therapist is the perfect experts to advance, direct, endorse and oversee practice and exercises that empower individuals living with sickness to enhance their level of Physical function (UNAIDS et al, 2009).

## 2.2 Advantages of Exercise in HIV patient

Strength training improves muscle mass, strength and lean body mass .In addition,Other exercises such as aerobic exercises improve endurance and reduce stress.. Exercises improve the ratio of lean body mass to fat mass (Roubenoff, 2000). Additionally, according to Kevin E et al. exercise (combination of strength training and aerobic) will help to reduce the hypertriglyceridemia (Yarasheki et al., 2001).

Moreover, people infected with HIV encounter various additional diseases due to the progression of the disease, medications, absence or insufficient muscle strength to perform physical moments and poor healthy sustenance, or a mix of these causes. Hand et al. further demonstrated that physical activity is a possible treatment of the significant number of HIV symptoms and side effects of the treatments. Also their study indicates that there are numerous benefits of exercises including increasing functional capacity, improvement of muscle strength, changes in HDL cholesterol, improving cognitive function, decreasing depression and anxiety and enhance the quality of life (Hand et al., 2009; Yarasheki et al., 2001)

Finally, according to above evidence, it shows that exercise training is beneficial for the PWLHA, though there is still a conflict of accessing the rehabilitation for PWLHA mainly in developing countries. This is due to the lack of Physiotherapists who are working in developing countries. For example according to the WHO statistics, when there is 20 Physiotherapist for 10000 populations in Finland there is only less than 2 Physiotherapist for 10000 populations in South Africa. Countries with high HIV positives have home-based and community-based rehabilitation projects. These projects are organized by UN and other organizations since they understand the value of exercises and the impact of rehabilitation on PWLHA (Cobbing et al, 2015).

### Strength Training and Physical Activity.

According to Paes et al, the long-term resistance training can be maintain strength and muscle girth in PWLHA and people who are undertreat highly active antiretroviral therapy (Paes et al., 2015). Souza et al mentioned that moderate one year period of strength training improves biomechanics and cardiovascular responses. Through improvement of biomechanics and cardiovascular responses, it facilitates the daily activities of life. Also, it states that Progressive strength training is beneficial for PLWHA without having any negative effects neither worsening of HIV related conditions (Souza et al., 2011).

According to the study done by Roubenof, exercises enhance and maintain body mass in addition other benefits. Relevant physiotherapy and occupational therapy treatments will increase functional status and exercise capacity in PLWHA. Moreover, it shows that high-intensity strengthening exercises have demonstrated particularly effect on improving muscle strength, muscle mass, and muscle circumference (Roubenof, 2001). Further, the study done by Yarasheski et al confirmed, ongoing strength training increases the lean body mass in HIV positive men by using magnetic resonance imaging. Using the same method it also proves that, how strength training helps to increase muscle hypertrophy in the thigh muscle. The percentage of increasing muscle strength was also imputable to increasing neural learning effect. Also, it shows that there is a direct connection between progressive resistance training and reducing hypertriglyceridemia in HIV positive men. It can be concluded that strengthening exercises are directly effective to control or reduce the metabolic complication of HIV (Yarasheski et al., 2001).



### 3 Objectives and Research Question

What is the effectiveness of strengthening exercises in endurance, muscle mass, muscle strength, Body weight and BMI and body fat in HIV positive patients ?

#### 3.1 Objectives

The complex multi-framework introduction of the ailment requires an all-encompassing and inventive way to deal with treatment. Supports of wellness, torment control, restoration, respiratory and palliative care are for the most part regions in which physiotherapy has a significant part. As individuals with HIV contamination live longer and the HIV commonness increments, there is a developing requirement for recovery and physiotherapy contribution (Cobbing et al., 2013).

This study will promote knowledge of understanding about HIV and strengthening exercises, to support PLWHA. Moreover, this modified literature review can be a motivation for a student who has the interest to study physiotherapy of HIV positive patients, and for a physiotherapist who is handling immunodeficiency cases.

Hence, This thesis focuses deeply on the strengthening exercises and its effects on PLWHA. This study offers a few assets for physiotherapists and physiotherapy students who are interested to expand their comprehension in strength training for HIV positives.

Therefore, the aim of this study is to systematically assess the effectiveness of strengthening exercises on muscle strength and endurance, muscle mass weight, BMI and body fat among HIV positive patients.

## 4 Methodology

A Literature review is the chosen method. The thesis was carried out from December 2017 to mid-April 2018. Search was done in the PubMed, CINAHL, Academic Search Elite and Cochrane Library databases (Figure 1). The keywords are effectiveness, effects, strengthening, strength, force, torque, exercises, training, rehabilitation, physical activity, and endurance, HIV/AIDS, physiotherapy and physical therapy. Physiotherapy and Exercises were used as the synonym for Physical therapy and training.

All the studies selected for this thesis are RCTs. This review will provide a combination of best available evidence. The inclusion and exclusion criteria are in Table 1.

Table 1: Inclusion and Exclusion criteria

	Inclusion Criteria	Exclusion criteria
Type of Research	Randomized control Trials (RCTs)	All other types of researches.
Clinical population and diagnosis	HIV positive patients	Pregnant HIV infected patients. Patients who are not confirmed as HIV positives.
Age and sex	Adults over 18 to 70 years old	Children and adults over 70 years of age
Articles	Articles which are available in Full text	Articles which are not available in full text.

All Selected articles were verified by The Joanna Briggs Institute Critical Appraisal tools for use in JBI Systematic Reviews (Checklist for Randomized Controlled Trials, 2017). The checklist is shown in appendix 2. The study flowchart is shown in figure 1.

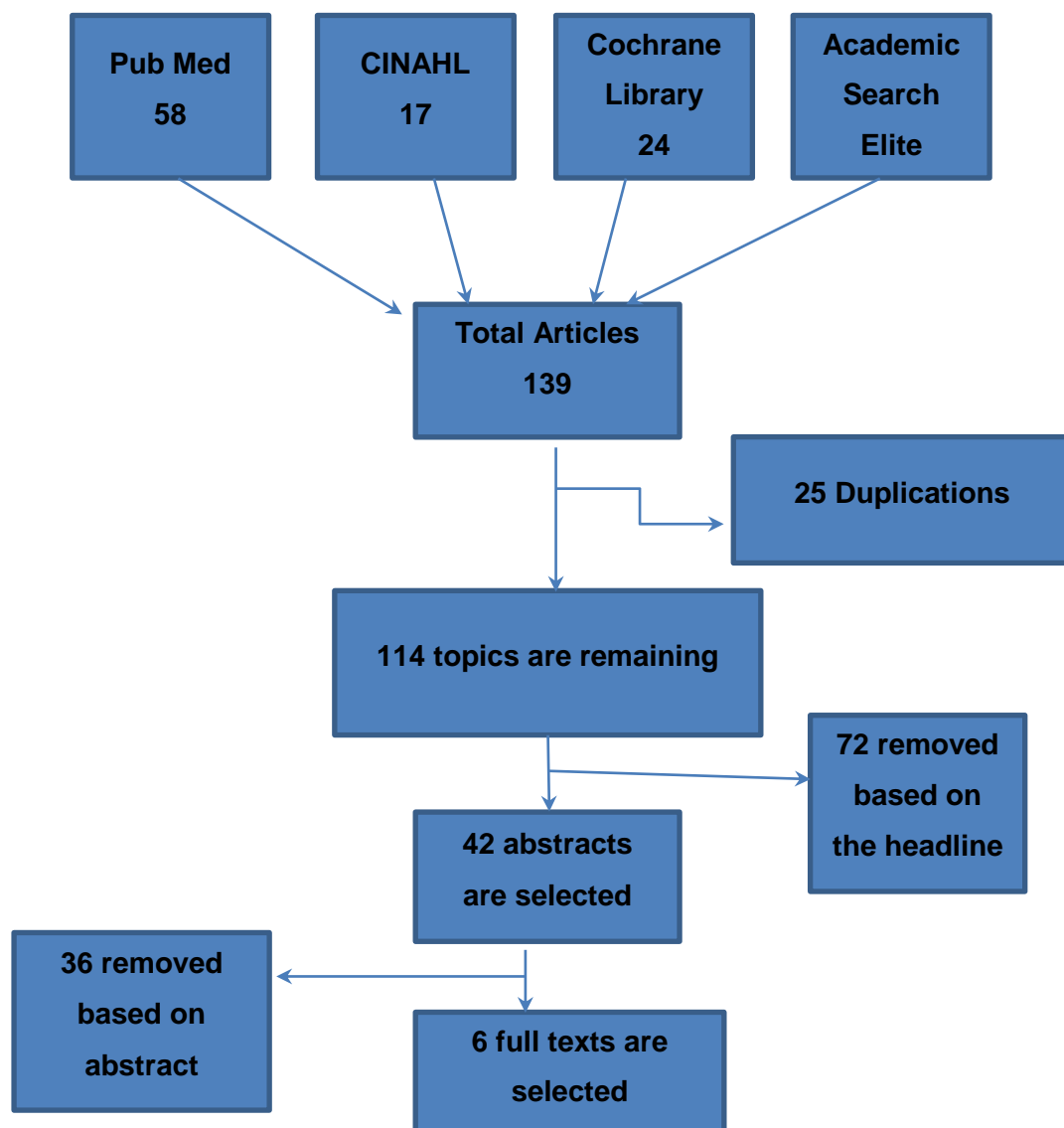


Figure 1. Study flowchart.

## 5 Results

According to the inclusion and exclusion criteria, 6 articles were selected for the study. Quality assessment is done by using the Joanna Briggs Institute (JBI) Critical Appraisal tools for use in JBI Systematic Reviews. All articles which selected got at least 7 in JBI tool. More results of the quality assessment are in table 2.

### 5.1 Muscle Strength and Endurance

Five of the six included studies assessed the Muscle strength as an outcome. As the table 2, it shows that almost every study it proved there is a significant improvement in the muscle strength. All studies mainly focused in about the major muscles such as biceps, triceps, calf, and hamstrings (Dolan et al., 2006; Paes et al., 2015; Patil et al., 2017; Bhasin et al., 2000; Agin et al., 2001). Further, most of the studies used free weights exercises for the training such as leg pressing, biceps and triceps curls and bench pressing (Dolan et al., 2006; Patil et al., 2017; Bhasin et al., 2000). However, Agin et al. used multi-gym apparatus for their study while Paes et al. used both free weights and machines for the strength training (Paes et al., 2015; Agin et al., 2001). Donald et al. and Patil et al. found that there is a significant increase in endurance where endurance—exercise time calculated by the submaximal bicycle test (Donald et al., 2006; Patil et al., 2017). According to table 2, almost every study proved there is a significant improvement in the muscle strength. Further details are available in appendix 1.

### 5.2 Muscle mass

out of eight articles , four studies discussed muscles mass as an outcome. Most of the studies were discussed that there is a positive result after engaging with the period of resistance training exercises. According to Dolan et al, strength training alone or collaborated with aerobic indicated improved strength and muscles mass among HIV positive men and women. (Dolan et al, 2006). Bhasin et al. reported that both exercise and testosterone alone groups got higher improvement in muscle volume than the placebo-alone group and exercise alone group (Bhasin et al., 2000). Furthermore, the study was done by Agin et al showed resistance exercise increase the muscle mass (Agin et al., 2001).

### 5.3 Body weight and BMI

All six involved studies investigated the body weight and BMI as an outcome; According to Dolan, there are no differences in Body Mass Index between intervention group and control group. (Dolan et al., 2006). Moreover Ghayomzadeh et al. also found that there is no significant difference between control (non-exercise) and intervention (exercise treated) group in body weight and BMI ( Ghayomzadeh et al., 2017). Agin et al. and Paes et al. also showed that there is no noticeable change in body weight during the study due to the resistance training (Agin et al., 2001; Paes et al., 2015). However, the study was done by Bhasin et al. reported that body weight was stable in control group were people who did strength training increased their body weight significantly (Bhasin et al., 2000)

### 5.4 Body Fat

Ghayomzadeh et al. found that control group remarkably increased their percentage of body fat, whilst intervention group significantly decreased their percentage of body fat after 8 weeks of study. Therefore, it also reported that there is a significant difference between both control and intervention groups in body fat. (Ghayomzadeh et al., 2017). Moreover, Agin et al. also reported that fat mass decreased in the group who did resistance training. Further, the study showed there was a significant difference between non-exercise and exercise treated group in fat mass (Agin et al., 2001). However, Dolan et al and Bhasin et al reported a different outcome than the Ghayomzadeh et al and Agin et al. Dolan et al, Paes et al, and Bhasin et al found that there is no significant difference between control non-exercises group and Intervention or exercise treatment group. (Dolan et al., 2006; Bhasin et al., 2000; Paes et al., 2015)



Table 2: Results with validation

Study	Purpose of the study	Methods, participants, main outcome/outcomes	Main results	Conclusions	Validation assessment
Patil et al 2017 India	To investigate the effects of moderate intensity physical exercises on fitness parameters and Quality of Life in HIV positive females.	A randomized, single-blinded, double control.  40 HIV positive females under ART for 2-5 years. and 15 HIV negative females, age – 20-40 years. Main Outcomes – Muscle strength and endurance, quality of life.	There is a significant improvement in muscle endurance with moderate intensity and muscle strength in the experimental group. But there was not any remarkable improvement observed in HIV control group.	Moderate intensity strength training improves quality of life and physical fitness parameters in HIV positive females.	Yes – 7 No – 5 Unclear - 1



Paes et al Brazil 2015	To assess long-term effects of the exercise program on the body composition and muscle function in HIV positives.	<p>A randomized control trials.</p> <p>A training program including aerobic, strength and flexibility exercises.</p> <p>27 HIV positive participants under HAART for at least 12 months (17 men/ 10 women)</p> <p>age: adults over 18 years.</p> <p>used a program with aerobic, strength and flexibility exercises.</p> <p>Main Outcomes – Body composition, muscle strength, and prevalence of sarcopenia.</p>	<p>Body weight is stable in the control group and significantly increased in strength training group.</p> <p>Muscle strength was remarkably increased on intervention group.</p>	Long-term supervised strength training program is adequate to increase muscle strength and muscle mass in HIV positives who are under HAART	<p>Yes – 8</p> <p>No – 4</p> <p>Unclear – 1</p>
Dolan et al United States 2006	To investigate effects of a Supervised Home-Based Progressive Resistance Training and Aerobic exercises in Women with HIV.	<p>A randomized control trial</p> <p>40 women with HIV, and self-reported fat redistribution.</p> <p>Age between 18 to 60 years and waist-hip ratio is greater than 0.85.</p> <p>Exercises protocol followed general guidelines of the American College of Sports Medicine.</p>	<p>Muscle strength and muscle mass significantly increased in all experimental muscle groups.</p> <p>No remarkable change was seen in the body fat and BMI.</p>	Home-based progressive training increased physical fitness and muscle strength in HIV positive women. Enhancement of cardiorespiratory	<p>Yes - 10</p> <p>No - 3</p>

		<p>strength training includes the shoulder abduction, arm curls. bench press, knee-hip extension, knee flexors and standing calf raises.</p> <p>Main Outcomes – Cardiorespiratory fitness and muscle strength.</p>		<p>fitness and endurance was seen.</p>	
<p>Agin et al 2001 United States</p>	<p>To assess the effects of resistance training, whey protein, and combined protein and exercise treatment on mass, muscle body cell, muscle strength, and quality of life in HIV positive women.</p>	<p>Prospective, randomized, controlled trial 30 HIV-infected women, age - from 28 to 66 years.</p> <p>Main Outcomes- body weight, Body cell mass, skeletal muscle, fat mass, muscle strength, and quality of life.</p>	<p>There were remarkable changes in muscle strength, body cell mass, skeletal muscle, muscle mass and quality of life and decreased fat mass in exercises group. Whey protein group increase fat without changing body cell mass and skeletal muscle.</p>	<p>Strength training remarkably increased body cell mass, muscle mass, muscle strength, and quality of life in HIV positive women.</p>	<p>Yes – 8 No – 4 Unclear - 1</p>

Bhasin et al 2000 United States of America	To investigate the effects of testosterone therapy inclusive and exclusive resistance exercise on body composition and muscle strength in HIV-positive men with weight loss and low testosterone levels.	Placebo-controlled, double-blind, randomized clinical trials.  61 HIV positive men aged 18 - 50 years and serum testosterone levels of lower than 12.1 nmol/L also weight loss greater than 5% in the past 6 months,  Outcomes - Changes in muscle strength, body weight, thigh muscle volume, and lean body mass.	Body weight, muscle mass, and muscle strength increased significantly in men receiving testosterone and exercise alone	Study shows the testosterone and resistance exercise improves body weight, lean body mass, muscle mass and muscle strength in men with HIV.  Intervention alone gave significant results than testosterone and exercise together	Yes – 11 No - 2
Ghahramani et al 2017 Iran	to assess the effects of 8-weeks of hospital-based strength training using elastic bands on immune competence and anthropometric indices	Randomized Control Trial 21 HIV positive participants. age over 18 years Outcomes - TCD4+ cell counts and body anthropometry.	TCD4+ count is significantly increased with resistance training. fat mass and lean body mass remarkable decrease in the intervention group and	Resistance training is effective for increasing TDC4+, lean body mass and body composition, decreasing body fat percentage and fat	Yes – 10 No -2 NA - 1

	in HIV positives.		increased in control group.	mass in HIV positives.	
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## 6 Discussion

In the searches, there was only 6 matched for the inclusion criteria. It will be better if the study find more related researches when developing this as the proper systematic review.

All the studies used the different protocols for their intervention which includes different study period, different resistance exercises, different intensity, different duration per session and sessions per week. Only Agin et al. mentioned about the standard guideline that they used for their resistance exercises which are American College of Sports Medicine guidelines (Agin et al., 2001). However, though it reported that muscle strength improved due to the resistance training it is difficult to compare when the studies used the different programs. Therefore it is recommended to use and mention standard guidelines when creating the intervention in the future.

Though most studies measured muscle strength as their outcome only two studies focused on the endurance. Since muscle strength and endurance is closely related to each other's, it is advisable to consider endurance as an outcome for further studies.

Though it is difficult to compare due to the different protocols that they used for interventions, All the four studies mentioned that resistance training improved the muscle mass. Also, it was admirable the studies which used other substances or type of exercises with exercise training reported how muscle mass and other factors changed individually and with the combination (Dolan et al., 2006; Agin et al., 2001; Bhasin et al., 2000).

Though most studies discussed body weight, BMI and body fat, it was still controversial the results they got. Hence it is highly recommending to conduct randomized control trials mainly focusing on how it affects to body weight, BMI and body fat on HIV positives. Also, it is advisable to use standard measurements and programs for the future interventions which focus on body weight, BMI and body fat.

As mentioned HIV positives are having decreased immune function, increased fatigability and other symptoms. However, most of the studies which used for this thesis did not mentioned clearly about the precautions and the specials matters that they should consider when planning the resistance training for special study

group like HIV positives. Quality of living is also the main effect which could consider in these kinds of studies because HIV and its symptoms are directly affecting HIV positives day to day life. However, only one study was focus on the Quality of life in HIV positives with their intervention (Agin et al., 2001). Therefore, it is recommended for future researchers to focus on the quality of life also as an outcome of their studies.

Finally, though findings are limited to minor sample size, low number of studies with HIV positive participants with different features, muscle strength and muscle mass remarkably increased because of strength training. Due to strengthening exercises, there was the reduction in body fat and improvement in endurance noticed even though, body weight and BMI were tentative.

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## Appendix


Study	Type of exercise	Intensity	Volume	Freq. (x per week)	Time (min)	Length (wk.)	Outcome
Dolan et al 2006	Resistive exercise Free Weights (standing calf raises, bench press, lateral raises, arm curls)	60-70% RM/2 80% RM/12	5 min warm-up  20-30 min exercise	3	35	16	Significant improvement of 1 repetition maximum in shoulder abductors, pectoralis, elbow flexors, the knee extensors, knee flexors and ankle plantar flexors.
Patil et al.	Resistance	Moderate	5 minutes	5	30	8	There is a

2017	Training (bench press, seated back row, shoulder press, biceps curls, triceps extension, leg extension, leg curl, squats)	intensity (50% - & 70% of VO2 max	warm-up 20 minutes exercises 5 minutes cool down				significant improvement in all the muscle groups after 8 weeks
Bhasin et al. 2000	Resistance training including, leg press leg curls, bench press and latissimus pulls.	1st 4 weeks - high volume low intensity (60%) 5-10 weeks - high intensity (70% - 90%) low volume 11- 16 weeks - loads and		1st 4 weeks - 3 5 - 10 weeks - 5		16	Exercise group got improvement in muscle strength in five exercises, testosterone group increased strength.

		number of sets increased.					
Agin et al. 2001	Progressive resistance training on a multi-gym apparatus	three sets of 10 exercises at 8–10 repetitions per set as per American College of Sports Medicine guidelines	warm up done prior to the strength training.	3		14	Maximum dynamic muscle strength for the exercise groups significantly increased for all seven muscle groups trained (range of increase 40.6–95.3%)
Paes et al. 2015	Strength training (free weights and machines)	80-90% of 12 repetition maximum	2 sets of 6 to 8 exercises with 30- to 8 exercises with	3	60 to 90 min	2 years (all month of the year except one month)	After 1 year, men showed significant enhancement

			30-s duration				in the maximal strength in relation to baseline, in both extension and flexion. women showed to be stable along 1 year of training. Subsequently, 2 years both women and men sustain their muscle strength
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Appendix 1: Effect on muscle strength



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### JBI Critical Appraisal Checklist for Randomized Controlled Trials

Reviewer \_\_\_\_\_ Date \_\_\_\_\_

Author \_\_\_\_\_ Year \_\_\_\_\_ Record Number \_\_\_\_\_

	Yes	No	Unclear	NA
1. Was true randomization used for assignment of participants to treatment groups?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Was allocation to treatment groups concealed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Were treatment groups similar at the baseline?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Were participants blind to treatment assignment?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Were those delivering treatment blind to treatment assignment?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Were outcomes assessors blind to treatment assignment?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Were treatment groups treated identically other than the intervention of interest?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Was follow up complete and if not, were differences between groups in terms of their follow up adequately described and analyzed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Were participants analyzed in the groups to which they were randomized?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Were outcomes measured in the same way for treatment groups?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Were outcomes measured in a reliable way?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Was appropriate statistical analysis used?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. Was the trial design appropriate, and any deviations from the standard RCT design (individual randomization, parallel groups) accounted for in the conduct and analysis of the trial?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Overall appraisal: Include ☐ Exclude ☐ Seek further info ☐

Comments (Including reason for exclusion)

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Critical Appraisal Checklist  
for Randomized Controlled Trials 3

Appendix 1: JBI Checklist for Randomized Controlled Trials.